ISRCTN21518741 https://doi.org/10.1186/ISRCTN21518741

Implementation of a pilot cervical cancer screening program based on single visit approach and improving capacity for breast cancer early diagnosis in Benin, Chad, Cote d' Ivoire, Senegal and Cameroon

Submission date
25/06/2019

Recruitment status
No longer recruiting

Registration date
16/07/2019

Overall study status
Completed

Last Edited
14/09/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Current plain English summary as of 04/02/2022:
Background and study aims
The present study aims to set up and look at the feasibility of implementing cervical cancer early detection through routine primary health care services in the country. It is expected that the study will help further large scale introduction of a screening programme in the country. The researchers also expect to improve the capacity of at least one tertiary care hospital in each country to perform quality assured diagnostic breast ultrasound and mammography, fine needle aspiration cytology (FNAC), histopathology and breast surgery.

Who can participate?
All women between 30 to 49 (or 25-49) years of age attending the selected primary health centres are invited to participate in the VIA/HPV – screen-and-treat screening programme.

What does the study involve?
Nurses/midwives/GPs examine and check possible changes on the surface of the cervix after applying diluted acetic acid (vinegar). If any abnormality is identified in the surface lining of the cervix, nurses/midwives/GPs advise immediate treatment by thermal ablation if the lesion is fully visible, involves less than 75% of the surface and there is no suspicion of invasive cancer. If the lesion is not suitable for thermal ablation, nurses/midwives/GPs refer the women to a diagnostic centre to be examined by colposcopy. All women with colposcopically suspected high-grade lesions receive Loop electrosurgical excision procedure (LEEP) treatment on the same day without waiting for histopathological verification. The screen-negative women are advised to repeat VIA after 3 or 5 years according to the national protocol of each country. The treated women are advised to attend the primary health centre for follow up after 12 months. The VIA test is repeated. Women having persistent lesion are referred to the diagnostic centre for treatment by LEEP. Those diagnosed with cervical cancer are directly referred to the oncology

centres to receive further staging investigations and treatment as required. No intervention is done that is new or not part of standard of care. No additional visits only for research purposes are required.
A proportion of women in Cameroon will be screened using HPV test. HPV-positive women with High-risk HPV 16 and HPV 18 will be treated by thermal ablation. The positive women with others types of HPV will be triaged with VIA. The treated women will be advised to attend the primary care clinic for follow up after 12 months. The HPV test will be repeated. The HPV-positive women will be referred to diagnostic centre.

What are the possible benefits and risks of participating?
Research participants will have free access to cervical cancer screening, follow-up and appropriate treatment if and when required and the experience gained from this project will help to improve health care for women in all those selected countries. The diagnostic facilities for breast cancer will also be improved in the participating countries. This will also benefit the community. Research participants could experience some pain during the insertion of the speculum, sensation of stinging or burning in their vagina caused by the diluted acetic acid (5 %) used for VIA or having vaginal discharge few days after the test. Women testing positive for human papillomavirus (HPV) infection could experience increased levels of anxiety that have been attributed to fears of stigmatization and developing cervical cancer. A proportion of patients treated by thermal ablation could experience mild side effects such as: watery discharge, mild or moderate pain, cramps, vasovagal reactions. Complications of thermal ablation like bleeding, pelvic infection are extremely rare. Complications may occur in about 1% to 2% of patients. Undergoing loop electrosurgical excisional procedures may cause bleeding, infection and cervical stenosis and incompetence. All these complications and side effects are linked to routine management of the participants. However, the researchers will ensure appropriate treatment and adequate care if that happened to any participant. There will be no interventions that will be for research purposes only.

Where is the study run from?
The study was conducted in Benin, Cote d'Ivoire, Senegal, and Cameroon in four or five primary health centres of those countries.

When is the study starting and how long is it expected to run for?
The study was initiated in April 2018 in Senegal, in July 2018 in Cote d'Ivoire, in May 2019 in Benin, and in January 2021 in Cameroon for a duration of 18 months from the start date in each country.

Who is funding the study?
Lalla Salma Foundation for prevention and treatment of cancers (Morocco)

Who is the main contact?
1. Dr Partha Basu as principal investigator from International Agency for Research on Cancer (IARC) (basup@iarc.fr)
2. Dr Yacine Dieng as local principal investigator from Senegal
3. Dr Denise Kpebo as local investigator from Cote d'Ivoire
4. Dr Djima Patrice Dangbèmey as local principal investigator from Benin
5. Dr Nkele Ndeki Ngohfrom as local principal investigator Cameroon

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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

Nil known

Study information

Scientific Title
Implementation of a pilot cervical cancer screening program based on single visit approach and improving capacity for breast cancer early diagnosis in Benin, Chad, Cote d'Ivoire, Senegal and Cameroon

Acronym
CARE4Afrique

Study objectives
Breast cancer is the commonest and cervical cancer is the fourth most common cancer, affecting women worldwide and are responsible for a large number of premature deaths especially in the sub-Saharan African countries. More than 85% of the cervical deaths occur in the less developed regions of the world with sub-optimal health system capacity to implement the multiple-visit based western model of cervical cancer screening program. Breast cancer incidence mortality is on the rise in the sub-Saharan African countries.

Most of the African countries will require specific recommendations on how to organize or improve cervical cancer screening services based on local evidence, which till date is very limited. The third edition of the Disease Control Priorities Project of the World Bank recommends opportunistic screening with VIA or HPV testing and treatment of precancerous lesions ('screen and treat' using single-visit or two-visits approach) as part of an essential package of health interventions in low-income countries, due to the high cost of population screening. Very few countries in sub-Saharan Africa have taken steps to introduce such 'screen and treat' programs. Sporadic VIA-based screening activities are going on in some of the countries with no proper evaluation and quality assurance. The experiences gained from properly implemented pilot projects will inform pragmatic decision making by the policy makers to scale up the programs.

The Disease Control Priorities project also identified early diagnosis of symptomatic women linked with access to good quality surgery and subsequent treatment as the most pragmatic essential strategy to tackle the growing burden of breast cancer in the countries with basic or limited resource environments. Providing the basic components of cancer early diagnosis in an equitable and timely manner through cancer health awareness, accurate clinical, radiological and pathologic diagnosis, and quality and affordable treatment can make a significant improvement in breast cancer control in the LMICs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 04/02/2022:
1. Approved 17/10/2017, IARC Ethics Committee (IARC Ethics Committee: 150 cours Albert Thomas, 69372 Lyon cedex 08, France; +33 (0)4 72 73 83 41; iec-secretariat@iarc.fr), ref: IEC Expedite Review
2. Approved 07/09/2018, National Ethics Committee for Health Research of Benin (National Ethics Committee for Health Research of Benin: BP 01-882 Benin, Cotonou, 01882, Benin; +229 (0)21 33 2178; info@sante.gouv.bi), ref: N_58/MS/DC/SGM/DRFMAT/CNERS/SA
3. Approved 21/06/2018, National Ethics Committee of Life and Health Sciences (National Ethics

Committee of Life and Health Sciences, 16 ème Etage-Tour C cité Administrative Abidjan-Plateau, Abidjan, 00225, Cote d'Ivoire; No telephone number available; ministere.sante@egouv.ci), ref: 078-18/MSHP/CNESVS-km
4. Approved 18/12/2017, Health Research of Senegal (Health Research of Senegal: Rue Aimé Césaire – Fann Residence, Darkar, 12500, Senegal; +221 (0)869 42 42; informatique@sante.gouv.sn), ref: Protocol SEN 17/65
5. Approved 22/07/2020, National Ethics Committee in Human Health Research (National Ethics Committee in Human Health Research: +237 677-944-889 / 677-757-330; centrecersh@gmail.com), ref: 2020/07/1267CE/CNERSH/SP

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Study design
Multicentric observational cross-sectional study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Cervical cancer

Interventions
Current intervention as of 04/02/2022:
All the consenting women between 30 to 49 years of age (or 25-49 years of age according to the national protocol) attending the clinics for different reasons will be offered visual inspection with acetic acid (VIA)/ human papillomavirus virus (HPV) opportunistically. All the VIA-positive women who have lesions suitable for ablative treatment (squamocolumnar junction fully visible, lesion is ectocervical, lesion size is less than 75% of the ectocervix, no suspicion of invasive cancer) will be offered treatment on the same day. HPV 16 and 18 positive women will be treated by thermal ablation. The positive women with others types of HPV will be triaged with VIA. The treated women will be advised to attend the primary care clinic for follow up after 12 months. VIA/HPV test will be repeated. Women with a persistent lesion or those who are HPV

positive will be referred to the diagnostic center for evaluation and treatment by Loop electrosurgical excision procedure (LEEP). The women with normal cervix at follow up will be advised routine screening after 3 or 5 years according to the national protocol of each country.

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Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 04/02/2022:
1. Participation in screening for each woman reported using the screening questionnaire at the screening visit
2. VIA/HPV positivity rate: Proportion of women positive on VIA/HPV among the total screened: calculated using the data collected by a questionnaire to record the VIA status of each screened woman at the screening visit
3. Treatment rate: Proportion of VIA/HPV-positive women eligible for thermal ablation who complete treatment at the same screening visit: calculated using the data collected by a questionnaire to record the completion of treatment at the same screening visit among VIA/HPV positive woman eligible for thermal ablation
4. Colposcopy compliance rate: Proportion of VIA/HPV-positive women referred to colposcopy who actually had the procedure done: calculated using the data collected by a questionnaire to record at colposcopy referral visit the compliance to colposcopy by VIA/HPV positive woman referred to colposcopy
5. Cure rate after treatment: Proportion of women treated by thermal ablation detected to be VIA/HPV negative at one-year follow-up visit after treatment out of the total number treated and followed up: calculated using the data collected by a questionnaire to record the VIA/HPV status after one year of each treated woman by thermal ablation
6. Complication rate after treatment: Proportion of complications reported after thermal ablation treatment out of the women treated: calculated using the data of reported complications after thermal ablation and recorded on a questionnaire

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Previous primary outcome measure:
1. Participation in screening for each woman reported using the screening questionnaire at the screening visit
2. VIA positivity rate: Proportion of women positive on VIA among the total screened: calculated using the data collected by a questionnaire to record the VIA status of each screened woman at the screening visit
3. Treatment rate: Proportion of VIA-positive women eligible for thermal ablation who complete

treatment at the same screening visit: calculated using the data collected by a questionnaire to record the completion of treatment at the same screening visit among VIA positive woman eligible for thermal ablation
4. Colposcopy compliance rate: Proportion of VIA-positive women referred to colposcopy who actually had the procedure done: calculated using the data collected by a questionnaire to record at colposcopy referral visit the compliance to colposcopy by VIA positive woman referred to colposcopy
5. Cure rate after treatment: Proportion of women treated by thermal ablation detected to be VIA negative at one-year follow-up visit after treatment out of the total number treated and followed up: calculated using the data collected by a questionnaire to record the VIA status after one year of each treated woman by thermal ablation
6. Complication rate after treatment: Proportion of complications reported after thermal ablation treatment out of the women treated: calculated using the data of reported complications after thermal ablation and recorded on a questionnaire

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/09/2022

Eligibility

Key inclusion criteria
All consenting women aged between 30 to 49 years (or 25-49) attending the primary health centers for different reasons will be offered VIA opportunistically

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
19552

Key exclusion criteria
1. Pregnant women
2. Women suffering from debilitating illnesses
3. Diagnosis of or previous invasive cervical cancer
4. Those screened for cervical cancer within the last 36 months

Date of first enrolment
01/04/2018

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
Benin

Cameroon

Côte d'Ivoire

Senegal

Study participating centre
FSU COM Edmond Basque
Plateau
Abidjan
Côte d'Ivoire
00225

Study participating centre
CSU 220 Logements
Adjame
Abidjan
Côte d'Ivoire
00225

Study participating centre
Service de SMI INSP
Adjame
Abidjan
Côte d'Ivoire
00225

Study participating centre
General Hospital of South Abobo
Abobo
Abidjan
Côte d'Ivoire
00225

Study participating centre
National Institute of Public Health
Boulevard Nangui Abrogoua
Abidjan
Côte d'Ivoire
00225

Study participating centre
GASPARD KAMARA
Amitie II
Dakar
Senegal
12500

Study participating centre
HLM
Square Hlm, HLM
Dakar
Senegal
125000

Study participating centre
MARISTES
Passerelle Hann Mariste
Dakar
Senegal
12500

Study participating centre
Liberte 6
Liberte 6 Extension
Dakar
Senegal
12500

Study participating centre
CHU MEL DE COTONOU
01 BP 107

Cotonou
Benin
01

Study participating centre
Hôpital de zone SURU LERE
Rue 1305
Cotonou
Benin
01

Study participating centre
Centre de santé de Missessin
06 BP 1497
Cotonou
Benin
06

Study participating centre
District Hospital, Akonolinga
Akonolinga
Cameroon
-

Study participating centre
Cameroon Baptist Health Services, Yaounde
Yaounde
Cameroon
-

Study participating centre
Women Health Promotion, Yaounde
Yaounde
Cameroon
-

Study participating centre
University Teaching Hospital, Yaounde
Yaounde

Cameroon
-

Sponsor information

Organisation
International Agency For Research On Cancer

ROR
https://ror.org/00v452281

Organisation
The Foundation Lalla Salma Cancer Prevention and Treatment

Funder(s)

Funder type
Charity

Funder Name
The Foundation Lalla Salma Cancer Prevention and Treatment

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be made available as per IARC policies on open science. Request for datasets should be directed to the IARC principal investigator (PI) Dr Partha Basu (BasuP@iarc.fr) with appropriate justification. To gain access, data requestors will need to sign a data access agreement. The data will be shared with investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. Individual participant data underlie the results reported in the published article after identification (text, tables, figures and appendices) will be shared. The data will be available from 9 months to 36 months following article publication. The data will be shared to achieve aims in the approved proposal.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	01/09/2022	14/09/2022	Yes	No